K081289 1 of 3

5. 510(k) SUMMARY

AUG - 4 2008

July 28, 2008

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Nanette Hedden
Manager, Global Regulatory Affairs
1620 Waukegan Rd. MPGR-AL
McGaw Park, IL 60085
Telephone: (847) 270-4871
Fax: (847) 785-5116

DEVICE NAME:

Trade name:
V-Link Antimicrobial Luer Activated Device and
Extension Sets with V-Link Antimicrobial Luer Activated Device

Table 5-1.
Product Codes for V-Link Antimicrobial Luer Activated Device

6N8399	V-Link Luer Activated Device with VitalShield
6N8378	Non-DEHP Catheter Extension Set with V-Link Luer Activated Device with VitalShield
6N8374	Non-DEHP Catheter Extension Set with V-Link Luer Activated Device with VitalShield
6N8377	Non-DEHP Y-Type Catheter Extension Set with V-Link Luer Activated Device with VitalShield
6N8371	Non-DEHP Y-Type Catheter Extension Set with V-Link Luer Activated Device with VitalShield

K081289 2 of 3

Common name: IV Administration Set

Classification name:

IV Administration Set (21 CFR 880.5440, Product Code FPA)

PREDICATE DEVICE:

Table 5-2.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
CLEARLINK Antimicrobial Luer Activated Device and Extension Sets with CLEARLINK Antimicrobial Luer Activated Device	Baxter Healthcare	K072576	November 6, 2007

DESCRIPTION OF THE DEVICE:

No design changes have been made to the V-Link Antimicrobial Luer Activated Device which was cleared on November 6, 2007. This submission adds supplemental data on the efficacy and durability of the antimicrobial coating.

The V-Link Antimicrobial Luer Activated Device consists of a clear housing encasing a gland and center post. The gland functions as the valve that provides a seal against the syringe/luer connector when the device is being used. The gland has a slit that opens when activated by the syringe/Luer connector. The gland also provides a surface that can be easily swabbed with antiseptic before each connection.

The hard surfaces of the V-Link Antimicrobial Luer Activated Device are coated with a proprietary silver technology that may reduce the growth of microorganisms on the coated surfaces of the V-Link device.

STATEMENT OF INTENDED USE:

Intended for use with a vascular access device for the administration of drugs and solutions. The V-Link Antimicrobial Luer Activated Device is an in-line injection site which can be connected to standard male Luer adapters (e.g., syringes or sets) for the continuous or intermittent fluid administration or the withdrawal of fluids.

The V-Link Antimicrobial Luer Activated Device contains an antimicrobial agent (metallic silver) that may reduce the growth of microorganisms on the coated surfaces of the V-Link device. The antimicrobial agent is not intended to be used as a treatment for existing infections.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Baxter V-Link Antimicrobial Luer Activated Device is substantially equivalent to Baxter's current legally marketed V-Link Antimicrobial Luer Activated Device cleared November 6, 2007 (K072576).

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use.

CONCLUSION:

The V-Link Antimicrobial Luer Activated Device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2008

Ms. Nanette Hedden
Manager, Global Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K081289
Trade/Device Name: V-Link Antimicrobial Luer Activated Device and
Extension Sets with V-Link Antimicrobial Luer Activated Device
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FMG
Dated: May 6, 2008
Received: May 7, 2008

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081289

Device Name:

V-Link Antimicrobial Luer Activated Device and

Extension Sets with V-Link Antimicrobial Luer Activated Device

Indications for Use:

Intended for use with a vascular access device for the administration of drugs and solutions. The V-Link Antimicrobial Luer Activated Device is an in-line injection site which can be connected to standard male Luer adapters (e.g., syringes or sets) for the continuous or intermittent fluid administration or the withdrawal of fluids.

The V-Link Antimicrobial Luer Activated Device contains an antimicrobial agent (metallic silver) that may reduce the growth of microorganisms on the coated surfaces of the V-Link device. The antimicrobial agent is not intended to be used as a treatment for existing infections.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081289